

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Maria Cristina Rosa Geroni, et al.	Examiner:	Unassigned
Serial No:	10/549,714	Art Unit:	Unassigned
Filed:	September 16, 2005	Docket:	17803 (PC27338A)
For:	COMBINED THERAPY COMPRISING NEMORUBICIN AND A CYCLOOXYGENASE-2-INHIBITOR	Dated:	October 26, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 4,672,057, dated June 9, 1987 to Bargiotti et al.;
2. United States Patent No. 4,710,564, dated December 1, 1987 to Otake et al.;
3. European Patent Publication No. 0 434 960 A1, published July 3, 1991;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Dated: October 26, 2005


Peter I. Bernstein

4. UK Patent Publication No. GB 2 247 885 A, published March 18, 1992;
5. Lewis A.D. et al., "Role of Cytochrome P-450 from the Human CYP3A Gene Family in the Potentiation of Morpholino Doxorubicin by Human Liver Microsomes", *Cancer Research* 52(16):4379-4384 (1992), XP-001182477;
6. United States Patent No. 5,466,823, dated November 14, 1995 to Talley et al.;
7. German Patent Publication No. DE 195 47 958 A1, published June 27, 1996;
8. UK Patent Publication No. GB 2 294 495 A, published May 1, 1996;
9. United States Patent No. 5,633,272, dated May 27, 1997 to Talley et al.;
10. United States Patent No. 5,840,924, dated November 24, 1998 to Desmond et al.;
11. UK Patent Publication No. GB 2 325 067 A, published November 11, 1998;
12. PCT International Publication No. WO 98/03484, published January 29, 1998;
13. United States Patent No. 5,932,598, dated August 3, 1999 to Talley et al.;
14. Achiwa H. et al., "Prognostic Significance of Elevated Cyclooxygenase 2 Expression in Primary, Resected Lung Adenocarcinomas", *Clinical Cancer Research* 5:1001-1005 (1999);
15. Masunaga R. et al., "Cyclooxygenase-2 Expression Correlates with Tumor Neovascularization and Prognosis in Human Colorectal Carcinoma Patients", *Clinical Cancer Research* 6:4064-4068 (2000);
16. United States Patent No. 6,034,256, dated March 7, 2000 to Carter et al.;
17. PCT International Publication No. WO 00/25779, published May 11, 2000;
18. PCT International Publication No. WO 00/66093, published November 9, 2000;
19. PCT International Publication No. WO 00/38730, published July 6, 2000;
20. Rahman Md. A. et al., "Coexpression of Inducible Nitric Oxide Synthase and COX-2 in Hepatocellular Carcinoma and Surrounding Liver: Possible Involvement of COX-2 in the Angiogenesis of Hepatitis C Virus-Positive Cases", *Clinical Cancer Research* 7:1325-1332 (2001);

21. Beulz-Riche D. et al., "Metabolism of Methoxymorpholino-Doxorubicin in Rat, Dog and Monkey Liver Microsomes: Comparison with Human Microsomes", *Fundamental & Clinical Pharmacology* 15:373-378 (2001);
22. Fraier D. et al., "LC-MS-MS Determination of Nemorubicin (Methoxymorpholinyl-doxorubicin, PNU-152243A) and its 13-OH Metabolite (PNU-155051A) in Human Plasma", *Journal of Pharmaceutical and Biomedical Analysis* 30(3):377-389 (2002); and
23. Quintieri L. et al., "Cellular Pharmacology of PNU-159682, a Liver Microsomal Metabolite of Methoxymorpholinyl Doxorubicin (Nemorubicin; MMDX), *European Journal of Cancer* 38:S19 (2002), XP-004403484.

Reference nos. 3, 5, 7, 18, 19 and 23 were cited in a Search Report dated July 28, 2004 received from the European Patent Office. Applicants are submitting copies of the above-cited references, together with a copy of the Search Report. The relevance of above-identified reference nos. 3, 5, 7, 18, 19 and 23 has been described in the Search Report. The relevance of above-identified reference nos. 1, 2, 4, 6, 8-17 and 20-22 has been described in the specification.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. §1.97(b), no statement or fee is required.

Respectfully submitted,



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Registration No.: 43,497

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PIB:dg

Form PTO-1449 U.S. DEPARTMENT OF COMMERCE (REV. 7-80) PATENT AND TRADEMARK OFFICE <div style="text-align: center;">LIST OF PRIOR ART CITED BY APPLICANT</div> <div style="text-align: center;"><i>(Use several sheets if necessary)</i></div>				Atty. Docket No. (Optional) 17803 (PC27338A)		Application Number 10/549,714	
				Applicant(s) Maria Cristina Rosa Geroni, et al.			
				Filing Date September 16, 2005		Group Art Unit Unassigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA	4,672,057	6/9/87	Bargiotti et al.			
	AB	4,710,564	12/1/87	Otake et al.			
	AC	5,466,823	11/14/95	Talley et al.			
	AD	5,633,272	5/27/97	Talley et al.			
	AE	5,840,924	11/24/98	Desmond et al.			
	AF	5,932,598	8/3/99	Talley et al.			
	AG	6,034,256	3/7/00	Carter et al.			
FOREIGN PATENT DOCUMENTS							
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
		0 434 960 A1	7/3/91	EPO			
		GB 2 247 885 A	3/18/92	United Kingdom			
		DE 195 47 958 A1	6/27/96	Germany			
		GB 2 294 495 A	5/1/96	United Kingdom			
		GB 2 325 067 A	11/11/98	United Kingdom			
		WO 98/03484	1/29/98	PCT			
		WO 00/25779	5/11/00	PCT			
		WO 00/66093	11/9/00	PCT			
		WO 00/38730	7/6/00	PCT			
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
		Lewis A.D. et al., "Role of Cytochrome P-450 from the Human CYP3A Gene Family in the Potentiation of Morpholino Doxorubicin by Human Liver Microsomes", <i>Cancer Research</i> 52(16):4379-4384 (1992), XP-001182477					
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

**LIST OF PRIOR ART
CITED BY APPLICANT***(Use several sheets if necessary)***Atty. Docket No. (Optional)**

17803 (PC27338A)

Application Number

10/549,714

Applicant(s)

Maria Cristina Rosa Geroni, et al.

Filing Date

September 16, 2005

Group Art Unit

Unassigned

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		Achiwa H. et al., "Prognostic Significance of Elevated Cyclooxygenase 2 Expression in Primary, Resected Lung Adenocarcinomas", <i>Clinical Cancer Research</i> 5:1001-1005 (1999)
		Masunaga R. et al., "Cyclooxygenase-2 Expression Correlates with Tumor Neovascularization and Prognosis in Human Colorectal Carcinoma Patients", <i>Clinical Cancer Research</i> 6:4064-4068 (2000)
		Rahman Md. A. et al., "Coexpression of Inducible Nitric Oxide Synthase and COX-2 in Hepatocellular Carcinoma and Surrounding Liver: Possible Involvement of COX-2 in the Angiogenesis of Hepatitis C Virus-Positive Cases", <i>Clinical Cancer Research</i> 7:1325-1332 (2001)
		Beulz-Riche D. et al., "Metabolism of Methoxymorpholino-Doxorubicin in Rat, Dog and Monkey Liver Microsomes: Comparison with Human Microsomes", <i>Fundamental & Clinical Pharmacology</i> 15:373-378 (2001)
		Fraier D. et al., "LC-MS-MS Determination of Nemorubicin (Methoxymorpholinylidoxorubicin, PNU-152243A) and its 13-OH Metabolite (PNU-155051A) in Human Plasma", <i>Journal of Pharmaceutical and Biomedical Analysis</i> 30(3):377-389 (2002)
		Quintieri L. et al., "Cellular Pharmacology of PNU-159682, a Liver Microsomal Metabolite of Methoxymorpholinyl Doxorubicin (Nemorubicin; MMDX), <i>European Journal of Cancer</i> 38:S19 (2002), XP-004403484

EXAMINER**DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
17803 (PC27338A)

In Re Application Of: **Maria Cristina Rosa Geroni, et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/549,714	September 16, 2005	Unassigned	23389	Unassigned	Unassignd

Title:

COMBINED THERAPY COMPRISING NEMORUBICIN AND A CYCLOOXYGENASE-2-INHIBITOR

Address to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

OR

☐ the fee set forth in 37 CFR 1.17(p).

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
17803 (PC27338A)

In Re Application of: **Maria Cristina Rosa Geroni, et al.**

Application No. 10/549,714	Filing Date September 16, 2005	Examiner Unassigned	Customer No. 23389	Group Art Unit Unassigned	Confirmation No. Unassigned
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Title:

COMBINED THERAPY COMPRISING NEMORUBICIN AND A CYCLOOXYGENASE-2-INHIBITOR

Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

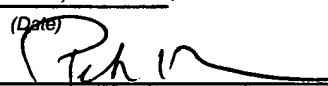
- ☐ A check in the amount of _____ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **19-1013/SSMP** as described below.
- ☐ Charge the amount of _____
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

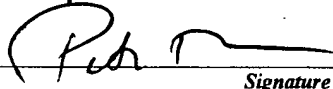
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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on **October 26, 2005** (Date)  Signature of Person Mailing Correspondence **Peter I. Bernstein**
Typed or Printed Name of Person Mailing Certificate

***This certificate may only be used if paying by deposit account.**


Signature

Dated: **October 26, 2005**

Peter I. Bernstein
Registration No. 43,497

CC: